Message

From: Tobias, David [Tobias.David@epa.gov]
Sent: 7/11/2017 7:08:57 PM
To: Aubee, Catherine [Aubee.Catherine@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]
Subject: RE: GenX Risk Assessment Knowledge Gaps

PS

The high water concentration in the study is the closer one to the mean measured value from the Cape Fear river. It is a realistic concentration to test.

David A. Tobias
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Risk Assessment Division (RAD)
Office of Pollution Prevention and Toxics (OPPT)
My office hours : 8:30 am - 5:00 pm

From: Aubee, Catherine
Sent: Tuesday, July 11, 2017 2:58 PM
To: Tobias, David <Tobias.David@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>
Subject: RE: GenX Risk Assessment Knowledge Gaps

Internal deliberative

So, what I think you are saying is

Ex. 5 - Deliberative Process

Do you both agree with this? Is this a sufficient response for Amy?

Best,
Catherine

From: Tobias, David
Sent: Tuesday, July 11, 2017 2:45 PM
To: Henry, Tala <Henry.Tala@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>
Subject: RE: GenX Risk Assessment Knowledge Gaps

Hello Tala

Ex. 5 - Deliberative Process

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From: Henry, Tala
Sent: Tuesday, July 11, 2017 2:14 PM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>; Tobias, David <Tobias.David@epa.gov>
Subject: RE: GenX Risk Assessment Knowledge Gaps

Ex. 5 - Deliberative Process

Tala R. Henry, Ph.D.
Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

T: 202-564-2959
E: henry.tala@epa.gov

From: Aubee, Catherine
Sent: Tuesday, July 11, 2017 2:09 PM
To: Henry, Tala <Henry.Tala@epa.gov>; Tobias, David <Tobias.David@epa.gov>
Subject: RE: GenX Risk Assessment Knowledge Gaps

Hi Tala,

Here is the proposed response. (I suggested deleting the strikeout section.) Any edits?

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Hello Amy

Thank you for reading the text closely.

As you point out below, the Hoke study presents data at two concentrations and indicated that the fish tissue concentrations were below quantitation at both test concentrations.

The author states that all bioconcentrations factors were < 30, probably because this is well below any regulatory cut-off. However, if the BCF was between 3 and 30, GenX should have been quantified in the high test concentration fish samples, but it was not.

Ex. 5 - Deliberative Process

I think that the current data indicates that BCF is likely less than 3 and both test concentrations indicate that the BCF is low.

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From: Henry, Tala
Sent: Tuesday, July 11, 2017 2:07 PM
To: Tobias, David <Tobias.David@epa.gov>
Cc: Aubee, Catherine <Aubee.Catherine@epa.gov>
Subject: FW: GenX Risk Assessment Knowledge Gaps

Are you addressing? Please express that either way, this is very LOW and indicative of low potential for accumulation in fish

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From: Risen, Amy J [mailto:Amy.Risen@dhhs.nc.gov]
Sent: Tuesday, July 11, 2017 8:20 AM
To: Aubee, Catherine <Aubee.Catherine@epa.gov>
Cc: Henry, Tala <Henry.Tala@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Doa, Maria <Doa.Maria@epa.gov>; Tobias, David <Tobias.David@epa.gov>
Subject: Re: GenX Risk Assessment Knowledge Gaps

Thank you for this. I do have a follow up question. You reported a BCF<3 and I wonder if that was a typo. Hoke et al reports a BCF<30 (BCF<3 for high concentrations and BCF<30 for low concentrations).

From: Aubee, Catherine <Aubee.Catherine@epa.gov>
Sent: Monday, July 10, 2017 12:15:49 PM
To: Risen, Amy J
Cc: Henry, Tala; Behl, Betsy; Strong, Jamie; Doa, Maria; Tobias, David
Subject: RE: GenX Risk Assessment Knowledge Gaps

Internal deliberative – joint work product

Hi Amy,

Thank you for sharing your meeting notes. We have a few clarifications that we'll send in a separate message. Meanwhile, here is the additional information that we discussed re: bioaccumulation potential.

Best,

Catherine

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Catherine Aubee

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- Estimating exposure potential due to fish consumption begins by assessing the potential for the build-up of a chemical in fish tissue relative to the concentration in the water. Laboratory test data for the accumulation in fish tissue based on long term exposures found that the ratio of the concentration of GenX in fish tissue to water, also known as the bioconcentration factor (BCF), was less than 3 (Hoke et al., 2016). This indicates long term exposures to GenX do not cause a significant buildup of the chemical in fish tissue and that long term exposures to GenX for people due to fish consumption would likely be significantly lower than drinking water exposures.
- Based on this BCF, GenX is considered to have a low bioaccumulation potential according to the EPA PBT Policy (U.S. EPA, 1999) and the Stockholm Convention (UNEP, 2009). The thresholds in these documents would require a BCF > 1000 or 5000 before a chemical became a concern for high bioaccumulation potential and these are significantly larger than those found for GenX.
- Per and polyfluoroalkyl substances (PFASs) have some properties which make them difficult to assess by traditional PBT classification schemes, but further evidence that the buildup of GenX will be lower than for PFOA (C8) comes from GenX having some properties that are more similar to shorter chain PFAS like PFHxA (C6).
    - GenX is more similar to smaller (or shorter chain length) PFAS (called C6 or C7) in molecular weight. Shorter chain PFAS have lower concern for fish tissue accumulation. Larger PFAS molecules (Above C9) have been found to accumulate in fish tissues.
    - GenX is not well removed from drinking water by activated carbon (Sun, 2016) which is similar to the shorter chain PFAS chemicals like C6. PFOA and longer chain PFAS in general have been found to have a better potential for drinking water treatment by activated carbon (Rahman 2014). This indicates that GenX may be less "sticky" to carbon than the PFAS that have been found to be a concern for fish bioaccumulation.
- The rate at which GenX is eliminated from the body after exposure has been measured in rats, mice and monkeys. These studies indicate that the elimination of GenX in all three organisms is relatively fast and it is not retained in body tissues (Gannon, 2016). This is substantially different than for some other perfluorinated chemicals, like PFOA, which is retained in monkeys and humans for significantly longer than in rodents (Lau, 2012). This is NOT the case for GenX; the retention in rodents and monkeys are about the same. This indicates that there is not a large difference among species in how quickly GenX may be cleared from the body and its behavior is different than PFOA. Although this is mammalian data, it is another indication that GenX has a lower tendency to accumulate in tissues than some other PFASs.

Gannon, SA; Fasano WJ; Mawn MP; Nabb DL; Buck RC; Buxton LW; Jepson GW; Frame SR (2016) Absorption, distribution, metabolism, excretion, and kinetics of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid ammonium salt following a single dose in rat, mouse, and cynomolgus monkey Toxicology 340: 1-9.

Hoke, RA; Ferrell, BD; Sloman, TL; Buck, RC; Buxton, LW. (2016) Aquatic hazard, bioaccumulation and screening risk assessment for ammonium 2, 3, 3, 3-tetrafluoro-2-(heptafluoropropoxy)-propanoate. Chemosphere 149: 336-342.

Lau, C. 2012 *Perfluoronated compounds*. Molecular Clinical and Environmental Toxicology. Vol. 3: Environmental Toxicology, ed. A. Luch, Birkhäuser-Verlag, Basel Switzerland, pp. 47-86.

Rahman, MF; Peldszus, S; Anderson, WB. (2013) Behaviour and fate of perfluoroalkyl and polyfluoroalkyl substances (PFASs) in drinking water treatment: A review. Water Research 50: 318-340.

UNEP (United Nations Environment Programme). (2009) Stockholm Convention on Persistent Organic Pollutants. Annex D. http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx

U.S. EPA (U.S. Environmental Protection Agency). (1999). Category for persistent, bioaccumulative, and toxic new chemical substances. Fed Reg 64: 60194-60204.

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